

VOLUME 4

STUDY TITLE

Bedoukian PMD Technical:
Waiver Request for the 90-Day Oral Toxicity Data Requirement

DATA REQUIREMENT

OCSPP Test Guideline: 870.3100

SPONSOR

Bedoukian Research, Inc.
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PREPARED BY

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COMPLETION DATE

September 13, 2019

NO CLAIM OF CONFIDENTIALITY

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Submitter: _____

Cinda L. Bell

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Agent for Bedoukian Research, Inc.

Date: _____

9/13/19

Bedoukian Research, Inc. (herein referred to as Bedoukian) is requesting a waiver of the 90-day oral toxicity data requirement (OCSPP 870.3100) for registration of their technical product, Bedoukian PMD Technical. Bedoukian PMD Technical contains 99.80% p-menthane-3,8-diol (i.e., PMD).

Per EPA's Preliminary Work Plan and Summary Document for p-menthane-3,8-diol, the 90-day oral toxicity study for PMD is not required because repeat oral exposure to PMD is not expected based on its use pattern (indoor use, applied directly to skin). In addition, PMD is not be applied to food. This document also concluded that the toxicological database is considered complete for characterizing hazard and assessing risk from PMD.

The Proposed Interim Registration Review Decision for PMD made the same conclusion as above and additionally stated that no additional studies are anticipated to be needed for registration review.

In addition, the 90-day oral toxicity study is only conditionally required for non-food uses. Per CFR footnote 6, the study is required for non-food uses that are likely to result in repeated oral exposure to humans. PMD is to be used as a skin repellent and there will be no oral exposure to humans. Therefore, this study is not required for this use.

Finally, no other registrants were required to submit the 90-day oral toxicity study to support registration of similar products; therefore, Bedoukian should also not be required to submit the study.

For the abovementioned reasons, Bedoukian is requesting a waiver of the 90-day oral toxicity data requirement (OCSPP 870.3100) to support registration of Bedoukian PMD Technical.